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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,125	08/14/2001	Susan Hand-Zimmermann	210121.544	9404

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 11/29/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/930,125

Applicant(s)

HAND-ZIMMERMANN ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-12 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3, 4, 5, drawn to an isolated polynucleotide composition encoding a polypeptide comprising an amino acid sequence consisting essentially of SEQ ID NO: 3 (10 amino acids in length), classifiable in class 536, subclass 23.1.
- II. Claims 2, 3, 4, 5, drawn to an isolated polypeptide comprising an amino acid sequence consisting essentially of SEQ ID NO: 3 (10 amino acids in length), classifiable in class 530, subclass 328.
- III. Claims 6, 7, 8, drawn to a method for eliciting an immune in a mammal comprising administering to the mammal an effective amount of an isolated polynucleotide composition encoding a polypeptide comprising an amino acid sequence consisting essentially of SEQ ID NO: 3, classifiable in class 514, subclass 44.
- IV. Claims 9 and 10, drawn to a method for eliciting an immune in a mammal comprising administering to the mammal an effective amount of an isolated polynucleotide having nucleotides 2026-3765 of SEQ ID NO: 1, classifiable in class 514, subclass 44.
- V. Claim 11, drawn to an isolated polynucleotide composition comprising the TCR-alpha sequence set forth in SEQ ID NO: 13, classifiable in class 536, subclass 23.5.

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- VI. Claim 12, drawn to an isolated polynucleotide composition comprising the TCR-beta sequence set forth in SEQ ID NO: 12, classifiable in class 536, subclass 23.5.

The inventions are distinct, each from the other because:

Inventions I and II, V, VI are distinct from each other because the polypeptide of Invention II is distinct in chemical structure and function, as well as therapeutic function from the polynucleotide of Invention I (DNA encoding SEQ ID NO: 3), V (SEQ ID NO: 13), or VI (SEQ ID NO: 12). Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and have different functions. Additionally, polynucleotide and polypeptide can be used in materially distinct methods. For example, the polynucleotides can be used for as detection probes or in a method of DNA therapy; polypeptide can be used for antigen presenting cell priming or peptide therapy. The difference between inventions I, II, V, and VI are further underscored by their different classification and independent search status.

Inventions I and III, IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated polynucleotide from Invention I can be used in materially different processes such as DNA therapy, method of producing proteins, method of producing a probe, a diagnostic assay or group IV. In addition, the method in group III can be

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used with a materially different product (nucleotides 2026-3765 of SEQ ID NO: 1) as shown in Group IV. The difference between inventions I and III, IV are further underscored by their different classification and independent search status.

Inventions II and III, IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated peptide from Invention II can be used in materially different processes such as peptide therapy, method of producing proteins, method of producing a probe, a diagnostic assay or group III or group IV. The difference between inventions II, III, and IV are further underscored by their different classification and independent search status.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because each of the methods of inventions III and IV constitutes patentably distinct inventions for the following reasons: Each of the inventions is directed to different goals and comprises materially distinct steps, wherein each of the compositions in each invention is structurally distinct and/or generates distinct mechanisms and functional effects as indicated above. For example, inventions III and IV are directed to distinct methods and structurally distinct compositions and are not directed to same methods. Furthermore, the scope of each of the cited inventions encompasses an employed method, which generates distinct function(s) and effect(s), and furthermore does not necessarily overlap with that of another invention. Each invention comprises materially distinct steps, and/or generate different functions and effects, and

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thus, are not required for use with one another. Therefore the invention of groups III and IV are distinct.

Because these inventions are distinct for the reasons given above and the literature search required for each Group is not required and not co-extensive for any other Group, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off.

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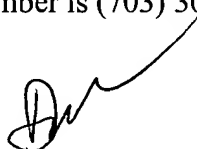
If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, primary examiner, Dave Nguyen can be reached at (703) 305-2024.

If attempts to reach the primary examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
1635
11/23/02



DAVE T. NGUYEN
PRIMARY EXAMINER